

DEC 11 2003

K033714

p112

510(k) SUMMARY

**SUBMITTER:** Dideco S.p.A.  
86, Via Statale 12 Nord  
41037 Mirandola (MO) Italy

**CONTACT PERSON:** Luigi Vecchi  
Phone: 011 39 0535 29811  
Fax: 011 39 0535 25229

**DATE PREPARED:** November 26, 2003

**DEVICE TRADE NAME:** MVR 1200 PC: Sorin Monolyth Venous Reservoir 1200 PC with phosphorylcholine coating (hereinafter called PC coating)

**COMMON NAME:** Softshell Venous Reservoir

**CLASSIFICATION NAME:** Reservoir, Blood Cardiopulmonary Bypass

**PREDICATE DEVICES:** MVR 1200 Sorin Monolyth Venous Reservoir (K933481),  
  
SYNTHESIS Adult Membrane Oxygenator with Integrated Arterial Filter and Hardshell Venous/Cardiotomy Reservoir Mimesys treated (Phosphorilcholine coating hereinafter called PC coating) (K022450),  
  
SYNTHESIS MIMESYS Adult Membrane Oxygenator with Integrated Arterial Filter and Hardshell venous/Cardiotomy Reservoir Mimesys Treated (PC coating) including the CVR 1200 PC with PC coating soft shell reservoir (K031223).

**DEVICE DESCRIPTION:**

Sorin Monolyth Venous Reservoir 1200 PC with Phosphorilcholine coating (hereafter referred to as the MVR 1200 PC) is a soft, flexible polyvinyl chloride plastic bag designed for use during extracorporeal bypass surgery as in-line venous bag reservoir. Blood contact surfaces of the MVR 1200 PC have been coated with phosphorylcholine (PC) coating. The PC coating improves blood compatibility, resulting in reduced platelet adhesion on the coated surfaces.

**INDICATION FOR USE:**

The MVR 1200 PC is a sterile, nonpyrogenic device intended for use as a storage reservoir for blood in an extracorporeal bypass circuit. The MVR 1200 PC must not be used for longer than 6 hours.

**TECHNOLOGICAL CHARACTERISTICS:**

The MVR 1200 PC is essentially identical to the MVR 1200 predicate device with respect to operating principles, control mechanisms and materials. The only modification made to the MVR 1200 PC is the extension of the coating material that bears the claim of reduced platelet adhesion on treated surfaces, to all blood contact surfaces of the softshell venous reservoir. The MVR 1200 PC shares the identical coating material, biocompatibility and manufacturing process of the PC coating with the Synthesis and the CVR 1200 PC coated (included in the Synthesis Mimesys) predicate devices.

The softshell venous reservoir is ethylene oxide sterilized and has a nonpyrogenic fluid path. It is for single use only. The device is not intended to be used for periods greater than 6 hours.

**BIOCOMPATIBILITY TEST RESULTS:**

A complete battery of tests were carried out in accordance with the requirements of ISO 10993-1:1995 and the FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing on the raw materials. Testing was performed on the MVR 1200 PC (accelerated aging). The device aged up to three years was tested for Hemolysis, Cytotoxicity, Irritation, Acute Systemic Toxicity and Mutagenicity. Sterility, Pyrogenicity, ETO residuals and package integrity testing were also conducted. The results of the testing met established specifications.

**IN VITRO TEST RESULTS:**

*In vitro* testing were carried out in accordance with the requirements of "Guidance for Blood Extracorporeal Blood Circuit Defoamer 510(k) Submission" Final Guidance for Industry and FDA issued on November 29, 2000 and the ISO 7199 (1996) standard for "Cardiovascular Implants and Artificial Organs – Extra Corporeal Blood-Gas Exchangers (Oxygenator)" when applicable for providing the data necessary to demonstrate both the substantial equivalence with the predicate device and also compliant with safety and effectiveness requirements. The device was aged up to 3 years and was tested for minimum operating blood volume, blood flow path, burst/leak testing, fill capacity, *in vitro* hemolysis/cell depletion, air removal efficiency and uniformity test of the PC coating. The results of these tests met established specifications. For comparative purposes, the same testing, when applicable, has been conducted also on the MVR 1200 predicate device. This 510(k) crosses reference performance data previously submitted in the Synthesis 510(k) (K022450) for blood compatibility characterization and in the Synthesis Mimesys 510(k) (K031223) for flaking and leaching studies in order to evaluate the stability of the coating.

The results of the study showed that the device characteristics between MVR 1200 PC and MVR 1200 were comparable.

**CONCLUSIONS:**

The results of *in vitro* studies demonstrate that the MVR 1200 PC device performs in a manner substantially equivalent to the predicate device. Biocompatibility studies demonstrate that the phosphorylcholine coating is biocompatible and functional tests demonstrate that its performance are equivalent to the MVR 1200 predicate device, according to its intended use. Additional testing has demonstrated the effectiveness of production techniques to assure that the soft shell venous reservoir is sterile and non-pyrogenic.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 11 2003

Dideco S.P.A.  
c/o Mr. Barry Sall  
Parexel International Corp.  
195 West Street  
Waltham, MA 02451-1163

Re: K033714  
MVR 1200 PC Sorin Monolyth Venous Reservoir 1200 PC with  
Pohosphorylcholine Coating  
Regulation Number: 21 CFR 870.4400  
Regulation Name: Cardiopulmonary Bypass Blood Reservoir  
Regulatory Class: Class II (two)  
Product Code: DTN  
Dated: November 26, 2003  
Received: November 26, 2003

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

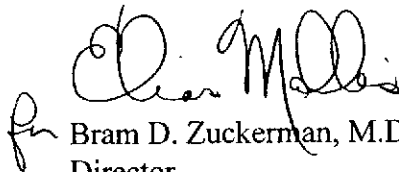
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.  
Director

Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K033714

Device Name: MVR 1200 PC Sorin Monolyth Venous Reservoir 1200 PC with  
phosphorylcholine coating

Indications For Use:

The MVR 1200 PC is intended for use as a storage reservoir for blood in an  
extracorporeal bypass circuit for periods up to six hours.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional format 1-2-96)



**(Division Sign-Off)**  
**Division of Cardiovascular Devices**

510(k) Number K033714